



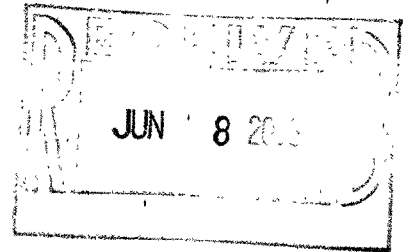
800 south frederick avenue
Gaithersburg, MD 20877

Telephone: 1 791 5 JUN 22 12:21 301-948-1041
Telefax:
Sales/Marketing/Finance 301-948-3194
General Administration 301-948-1862
Regulatory 301-948-8627
Corporate Affairs 301-948-2049

June 6, 2005

Via Federal Express

Office of Nutritional Products, Labeling
and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740-3835



AIMS#
2005-3431

Re: Section 6 Notification for ALCAR®

To Whom It May Concern:

On behalf of Sigma-Tau Pharmaceuticals, Inc., I am submitting this notification pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA). This notification letter contains the following information that is requested under 21 C.F.R. § 101.93(a).

Name and Address of the Distributor:

Sigma-Tau Pharmaceuticals, Inc.,
800 S. Frederick Ave.,
Gaithersburg, MD 20877

Text of the Statements:

- Supports mental focus
- Promotes energy metabolism in the brain
- Enhances memory and concentration

Name of the Dietary Ingredients in the Product:

- Acetyl-L-Carnitine

97S 0162

LET

16 326

ONPLDS
June 6th, 2005
Page 2

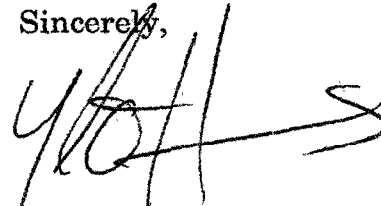
Brand name of the Dietary Supplement:

- ALCAR®

We certify that the information in this notice is complete and accurate and that the company has information that the statement is truthful and not misleading.

If you have any questions regarding this notice, please feel free to contact me at 301-670-1515.

Sincerely,

A handwritten signature in black ink, appearing to read 'Yamil Hernandez', with a long horizontal stroke extending to the right.

Yamil Hernandez

Product Manager